EXHIBIT B

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

LLOYD BELL, individually and)	
as Executor of the Estate of)	
Betty Whitley Bell, Deceased,)	
)	
Plaintiff,)	
)	
V.)	1:17CV111
)	
AMERICAN INTERNATIONAL)	FILED UNDER SEAL
INDUSTRIES, et al.,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

OSTEEN, JR., District Judge

Before this court is Northwell Health, Inc.'s ("Northwell") Motion for Reconsideration of its Motion to Intervene and Extend Protective Order. (Doc. 388.) Also before this court is a Motion to Vacate the Preliminary Protective Order of September 25, 2020, (Doc. 368), filed by Defendant American International Industries ("AII") and joined by Defendant Whittaker, Clark & Daniels, Inc. ("WCD"), (Doc. 373). Lastly before this court are motions to seal the motion to vacate and related briefing. (Docs. 370, 375, 378, 381.) The motion for reconsideration and motion to vacate will be granted; the motions to seal will be denied.

I. BACKGROUND

Betty Whitley Bell ("Mrs. Bell") worked most of her career as a hairdresser and used Clubman brand talc powder for over thirty years, beginning in the 1970s, (Doc. 294-9 at 6-8), and continuing through 2009, (id. at 7-8). All purchased the Clubman brand in the late 1980s. (Doc. 294-3 ¶ 8.) Mrs. Bell was diagnosed with mesothelioma in July 2015. (Doc. 322-2 at 2; Doc. 205-11 at 5-6.)

In September 2015, Mrs. Bell filed workers' compensation claims with the North Carolina Industrial Commission, asserting that she was exposed to asbestos during prior employment with two textile employers—Hoechst Celanese Corporation and Pillowtex Corporation. (Doc. 322-2.) Mrs. Bell's claims were eventually dismissed without prejudice. (Doc. 333-3.)

Mrs. Bell filed this case in February 2017, arguing that exposure to asbestos in Clubman talc powder caused her mesothelioma. (Doc. 1.) Mrs. Bell passed away in June 2017. (Doc. 39-2 at 2.) The executor of her estate, Lloyd Bell, was substituted as Plaintiff in this action after Mrs. Bell passed. (Doc. 40.)

 $^{^{1}}$ All citations in this Memorandum Opinion and Order to documents filed with the court refer to the page numbers located at the bottom right-hand corner of the documents as they appear on CM/ECF.

In April 2019, Plaintiff filed a new workers' compensation claim against Mrs. Bell's two former textile employers seeking death benefits.² (Doc. 322-5.) The claims were again dismissed without prejudice. (Doc. 333-11.)

In January 2020, the peer-reviewed Journal of Occupational and Environmental Medicine published an article titled "Mesothelioma Associated With the Use of Cosmetic Talc." (Doc. 274-1 at 2.) Dr. Jacqueline Moline was the article's lead author. (Id.) The article analyzed medical records and deposition transcripts for thirty-three anonymous individuals diagnosed with mesothelioma for whom Dr. Moline had conducted a "medico-legal evaluation as part of tort litigation." (Id.) The article stated that each of the thirty-three individuals had no known asbestos exposure other than talcum powder. (Id.) The article claimed to be "the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users." (Id. at 5.) Prior to drafting the article, Dr. Moline received Institutional Review Board ("IRB") approval from her employer, Northwell. (Doc. 2652-1 at 2; Doc. 392-1 at 2-4.) That approval referenced federal regulations governing human subject research and waived

² Both this and the prior workers' compensation filings were subject to a state statute that criminalizes the making of false statements to obtain benefits. N.C. Gen. Stat. § 97-88.2(a).

the requirement that Dr. Moline obtain informed consent from the individuals whose cases she planned to study. (Doc. 392-1 at 2-3.)

Dr. Moline's work has been influential. For example, after her article had been published online, she testified to Congress about her findings. (Doc. 331-11.) In her congressional testimony she used a pseudonym-"Ms. D"—to discuss one of the thirty-three individuals analyzed for her article. (Id. at 5-6.)

Dr. Moline had been retained as an expert in this case.

(See, e.g., Doc. 188-8.) Because the facts of Mrs. Bell's case paralleled the description of Ms. D in Dr. Moline's congressional testimony, AII suspected that Mrs. Bell was one of the thirty-three anonymous individuals that the article had studied. (Doc. 188 at 6-7.) If so, AII believed that would undermine the article's express premise and the related expert testimony that none of the individuals had any known exposure to asbestos other than talcum powder because Mrs. Bell and her estate filed workers' compensation claims alleging occupational exposure to asbestos from textile workplaces. (Id. at 3.) In a deposition for a different mesothelioma case, AII asked Dr. Moline for specifics about the thirty-three individuals. (See Doc. 188-1 at 6.) Dr. Moline declined to answer due to confidentiality concerns. (Id.) The plaintiff's counsel, who

also represents Plaintiff in this case, advised AII that if it sought information regarding the thirty-three individuals, then it would have to subpoena Northwell. (<u>Id.</u> at 6-7.) AII did so, (Doc. 168-1), and Plaintiff moved to quash the subpoena, (Doc. 168).

After AII provided Northwell with a HIPAA authorization form signed by Plaintiff, (Doc. 179-6), Northwell produced a single five-page document (the "Northwell Document"), (Doc. 182-5). The document is a spreadsheet containing information on all thirty-three individuals the article studied, but importantly the entire document is redacted except for the row headings and the column listing Mrs. Bell's information. (Id. at 4-8.) Upon learning that this document had been disclosed, Plaintiff filed an emergency motion for a protective order pursuant to Federal Rule of Civil Procedure 26(c) to preclude discovery and inquiry into the identities of the thirty-three individuals. (Doc. 182 at 5-9, 12.) The motion also sought for all copies of the Northwell Document to be destroyed and not disseminated in this case or any other forum. (Id. at 12.) The motion was set for hearing. (Text Entry 09/18/2020.)

On September 25, 2020, the Magistrate Judge held that the Northwell Document could be used in this case but that it, and the information therein confirming Mrs. Bell was one of the

thirty-three individuals the article studied, was "confidential and limited solely to this case." (Doc. 206 at 94, 96.) The Magistrate Judge explicitly stated that this limited protective order could potentially be reconsidered as the case progressed. (Id. at 96.) In December 2020, Northwell filed a Motion to Intervene and Extend Protective Order, seeking to prevent defense counsel from questioning Dr. Moline about any link between Mrs. Bell and the article. (Doc. 258.)

Before Northwell's motion was adjudicated, Plaintiff effectively withdrew Dr. Moline as an expert by not presenting her for deposition by the court-ordered January 7, 2021 deadline. (Order ("MJ's Order") (Doc. 309) at 3.) Accordingly, in February 2021, the Magistrate Judge denied Northwell's intervention motion as procedurally moot and untimely, as well as substantively meritless. (Id. at 3-8.) Northwell filed an objection, (Doc. 316), but this court affirmed the Magistrate Judge's decision, (Doc. 350 at 8).

In July 2021, this court granted AII's motion for summary judgment, and judgment was entered the following month.

(Doc. 361 at 12-13; See Doc. 366.) The case was closed.

On September 29, 2021, AII filed the instant motion requesting this court vacate the order protecting the identification of Mrs. Bell as one of the individuals in the

article from disclosure outside this case. (Doc. 368.) AII filed a brief in support of its motion. (Def. AII's Br. in Supp. of Mot. to Vacate Prelim. Protective Order of Sept. 25, 2020 ("AII's Br.") (Doc. 369).) Codefendant WCD filed a notice that it joins in AII's motion. (Doc. 373.) Plaintiff responded in opposition to the motion, (Pl.'s Resp. in Opp'n to AII's Mot. to Vacate Prelim. Protective Order of Sept. 25, 2020 & WCD's Notice of Joinder ("Pl.'s Resp.") (Doc. 377)), and AII replied, (Def. AII's Reply in Supp. of Mot. to Vacate Prelim. Protective Order of Sept. 25, 2020 ("AII's Reply") (Doc. 380)). In June 2022, Northwell filed a motion for reconsideration of its intervention motion, (Doc. 388), accompanied by a brief, (Northwell's Suppl. Mem. of Law in Supp. of Mot. for Recons. of Mot. to Intervene and Extend Protective Order ("Northwell's Recons. Br.") (Doc. 391)). That motion is unopposed. Northwell also filed a response in opposition to AII's motion to vacate the protective order, (Northwell's Resp. in Opp'n to AII's Mot. to Vacate Prelim. Protective Order of Sept. 25, 2020 & WCD's Notice of Joinder ("Northwell's Resp.") (Doc. 392)), to which AII replied, (Doc. 394).

The motion to vacate and related briefing, as well as Northwell's brief supporting its reconsideration motion, have all been filed under temporary seal and are accompanied by

corresponding motions to seal. (Docs. 370, 375, 378, 381, 390, 395.) AII and WCD state in their motions to seal that they do not believe the filings need to be sealed and have only filed motions to seal because Plaintiff and Northwell claim confidentiality. (Doc. 370 at 1-2; Doc. 375 at 1; Doc. 381 at 1-2; Doc. 395 at 1-2.)

II. ANALYSIS

The motion for reconsideration, motion to vacate the protective order, and the motions to seal are all ripe for review. This court will address the motions in that order.

A. Motion for Reconsideration

Northwell seeks reconsideration of its intervention motion so it can become an intervening party, allowing it to "adequately defend its continuing interests in this case."

(Northwell's Recons. Br. (Doc. 391) at 6.) The reconsideration motion is unopposed.

After carefully reviewing Northwell's reconsideration motion and supporting brief, (Doc. 388; Northwell's Recons. Br. (Doc. 391)), this court will grant the motion to the extent necessary to admit Northwell as a formal intervening party in

this case.³ Accordingly, this court has fully considered and herein addressed the relevant arguments contained in Northwell's response to AII's motion to vacate the protective order, (Northwell's Resp. (Doc. 392)).

B. Motion to Vacate Protective Order

As a threshold matter, the parties disagree what standard this court should apply in adjudicating the motion to vacate the protective order. AII⁴ insists that the Northwell Document is a judicial record. (AII's Br. (Doc. 369) at 12.) AII maintains that because the Northwell Document is a judicial record there is a presumption of public access that "can be rebutted only if 'countervailing interests heavily outweigh the public interests

³ Northwell's reconsideration motion was made pursuant to Federal Rule of Civil Procedure 54(b). (Doc. 388 at 1; see also Northwell's Recons. Br. (Doc. 391) at 4.) That is not the appropriate vehicle because Rule 54(b) reconsideration motions must be made "before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Here, such a judgment adjudicating all the parties' claims and liabilities has been entered. (Doc. 366.)

The appropriate vehicle for Northwell's reconsideration motion is Rule 60(b)(6), which allows this court to relieve a party from an order for any "reason that justifies relief." This court has carefully reviewed Northwell's motion and supporting brief pursuant to that Rule and finds that they provide sufficient grounds to justify relief from this court's prior order denying Northwell's intervention motion.

⁴ Although WCD has filed a notice that it joins AII's motion to vacate, (Doc. 373), for ease of reference this court will refer to AII as the party making the arguments in favor of vacating the protective order.

in access.'" (Id. at 13 (quoting BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc., 1:10cv276, 2013 WL 12178583, at *1 (M.D.N.C. Sept. 30, 2013)).) Plaintiff and Northwell disagree that the Northwell Document qualifies as a judicial record and contend that the motion to vacate must be justified by "good cause" pursuant to Federal Rule of Civil Procedure 26(c). (Pl.'s Resp. (Doc. 377) at 12; Northwell's Resp. (Doc. 392) at 7-8.)

"The type of documents or information which will be revealed by the modification to the protective order directly bears on the decision to modify. . . . [If] the documents are so-called 'judicial documents,' any presumption in favor of maintaining confidentiality must now contend with a presumption in favor of public access." SmithKline Beecham Corp. v. Synthon Pharms., Ltd., 210 F.R.D. 163, 167 (M.D.N.C. 2002). That right of public access "derives from two independent sources: the common law and the First Amendment." Va. Dep't of State Police v. Wash. Post, 386 F.3d 567, 575 (4th Cir. 2004). But "the mere filing of a document with a court does not render the document judicial." Hatch v. Demayo, No. 1:16cv925, 2020 WL 6161533, at *5 (M.D.N.C. Oct. 21, 2020) (internal quotation marks omitted) (quoting In re Policy Mgmt. Sys. Corp., 67 F.3d 296 (table), Nos. 94-2254 & 94-2341, 1995 WL 541623, *4 (4th Cir. 1995)).

Rather, "documents filed with the court are 'judicial records' if they play a role in the adjudicative process, or adjudicate substantive rights." In re. U.S. for an Order Pursuant to 18 U.S.C. Section 2703(d), 707 F.3d 283, 290 (4th Cir. 2013). Applying that definition, court filings may be judicial records if "they were filed with the objective of obtaining judicial action or relief." Id. at 291. Crucially, however, "courts in this circuit have found that documents filed to facilitate protective orders and other discovery motions do not qualify as judicial records." United States ex rel. Thomas v. Duke Univ., No. 1:17cv276, 2018 WL 4211375, at *4 (M.D.N.C. Sept. 4, 2018) (collecting cases). Fourth Circuit courts have ruled similarly regarding documents filed to facilitate motions to seal. E.g., id. (concluding that "motions to seal concern procedural issues similar to those requesting protective orders [and thus] . . . do not qualify as 'judicial documents'").

Here, AII argues that the Northwell Document is a judicial record because it was attached to AII's Opposition to Northwell Health's Objections and Appeal and "has also been the subject of numerous motions." (AII's Br. (Doc. 369) at 12.) But that Opposition to Northwell's Objections and Appeal and each of those motions were filed in relation to the protective order, discovery, or sealing requests. (See e.g., Docs. 168, 179, 331.)

Therefore, the Northwell Document does not qualify as a judicial record, and no presumptive right of public access attaches. <u>See</u>
United States ex rel. Thomas, 2018 WL 4211375, at *4.

Because no public right of access has presumptively attached, AII's motion is not governed by the First Amendment or common law but rather the "good cause" standard from Federal Rule of Civil Procedure 26(c), the rule providing for protective orders. While the rule itself does not address modification of protective orders, "[a] district court has discretionary authority to modify a protective order it has previously entered 'for what it deems good cause shown.'" Schaefer v. Fam. Med. Ctrs. of S.C., LLC, C/A No. 3:18-cv-02775-MBS, 2019 WL 2135675, at *12 (D.S.C. May 16, 2019) (quoting United States v. (Under Seal), 794 F.2d 920, 928 n.6 (4th Cir. 1986)); accord In re Kolon Indus. Inc., 479 F. App'x 483, 485-86 (4th Cir. 2012). As in this case, "[a] final judgment . . . does not diminish the district court judge's right to lift or to modify [protective] orders." Factory Mut. Ins. v. Insteel Indus., Inc., 212 F.R.D. 301, 303 (M.D.N.C. 2002). Because the parties did not stipulate to a protective order, and instead Plaintiff moved for a protective order during discovery and that motion was grantedthe finding of that good cause for the protective order was necessarily established, see Longman v. Food Lion, Inc., 186

F.R.D. 331, 333 (M.D.N.C. 1999)—"[t]he party seeking to modify a protective order bears the burden of showing good cause for the modification." SmithKline Beecham, 210 F.R.D. at 166.

In determining whether that party has shown good cause, courts consider four factors: "[1] the reason and purpose for a modification, [2] whether a party has alternative means available to acquire the information, [3] the type of protective order which is at issue, and [4] the type of materials or documents which are sought." Id.; accord Am. Heartland Port, Inc. v. Am. Port Holdings, Inc., 53 F. Supp. 3d 871, 880-81 (N.D.W. Va. 2014); Schaefer, 2019 WL 2135675, at *12. As will be discussed, the first factor weighs in AII's favor, the second in Plaintiff's favor, the third is neutral, and the fourth in AII's favor. This court finds that because more factors weigh in favor of vacating the order than preserving it, AII has met its burden to show good cause, and the protective order will be vacated. Each factor will now be addressed in turn.

1. Reason for Modification

AII seeks to vacate the protective order to allow for "public access to data that undermines claims that plaintiffs' experts and counsel continue to present to courts and fact-finders." (AII's Br. (Doc. 369) at 13.) AII explains that the purpose of its motion is "to prevent Moline and others from

misrepresenting to courts, juries, and the public the truth about a study supposedly showing that cosmetic talc causes mesothelioma." (Id. at 14.) AII argues that if the order protecting the Northwell Document is lifted, then it will be able to debunk "the false narrative that the only plausible asbestos exposures in the 33 cases were from contaminated cosmetic talc" because it will be able to show that at least one of the individuals the article studied, Mrs. Bell, "had alternative exposures to asbestos at her job sites." (Id. at 14, 16.) AII explains that it "and other defendants continue to be confronted with Moline's [a]rticle in litigation, and other plaintiffs' experts rely on it as support for their opinions." (Id. at 17.) AII asserts that plaintiffs in these other cases are using the protective order from this case "as a shield against cross-examination" to prevent the discrediting of the article. (Id. at 16.)

Plaintiff disagrees that the Northwell Document undermines the article's claims. (See Pl.'s Resp. (Doc. 377) at 15-16.)

Plaintiff insists that the workers' compensation claims do not establish that Mrs. Bell in fact had alternative exposure to asbestos at the textile workplaces; rather, those claims are merely unsupported allegations. (Id.) Moreover, Plaintiff and Northwell argue that "Defendants may effectively cross-examine"

Dr. Moline on the exact issue they have with the Moline Study without disclosing . . . Mrs. Bell's identity." (Id. at 16; see also Northwell's Resp. (Doc. 392) at 11.) Plaintiff points to trial testimony in a California state court case as an example. (Id.)

In essence, AII seeks to vacate the protective order so the Northwell Document can be used in other litigation. This is "the most forceful" grounds for modifying a protective order and "builds on a long line of cases recognizing the propriety of access to the fruits of one litigation to facilitate the preparation of other cases." 8A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 2044.1 (3d ed. Apr. 2022 update) But nevertheless "[a] court should be hesitant to modify protective orders for matters unrelated to the litigation in front of it because . . . modifying protective orders for other litigation involves re-litigation over issues that that have nothing to do with the lawsuit in front of the court . . . [and can] burden[] both the court and the parties." SmithKline Beecham, 210 F.R.D. at 166 (internal citation omitted). Moreover, "[s]uch modifications [risk] involv[ing] the court in a controversy with which it is not familiar and over which it lacks control." Id.

AII's reason for seeking to vacate the protective order seems to outweigh those concerns. While this court is hesitant to justify a modification of its own protective order solely in light of collateral cases, it also recognizes that the issues and controversies in those collateral cases intimately intersect with those litigated in this case. Further, although this court agrees with Plaintiff that the mere existence of the unsuccessful workers' compensation claims does not definitively establish that Mrs. Bell was in fact exposed to asbestos at the textile workplaces, Mrs. Bell nonetheless made statements to the Industrial Commission, while represented by counsel, that she had sustained an occupational disease caused by exposure to asbestos during employment with Hoechst Celanese Corporation and Pillowtex Corporation. (Doc. 322-2 at 2.) The alleged occupational disease was mesothelioma. (Doc. 322-3 at 2.) As Mrs. Bell's counsel explained, "[s]he made a [workers' compensation] claim because she thought she might have been exposed." (Doc. 322-7 at 6.) Mrs. Bell's employment history, as well as her belief that she may have been exposed to asbestos during her textile employment, undermines the weight of Dr. Moline's finding that each of the "33 cases . . . had no known exposure to asbestos other than prolonged use of talcum powder." (Doc. 274-1 at 5.) The fact is that at least one study

participant reported to a state agency that she did have another known asbestos exposure, at least one known to the study participant. Given the groundbreaking nature of the article and its express premise that all individuals studied had no known alternative asbestos exposures, the fact that one of the individuals claimed otherwise has direct bearing on the study's credibility. This court expressed concern about this seeming contradiction before, (Doc. 350 at 7 n.2), and does so again.

This court's concern is magnified considering the influence the article has had on cosmetic talc litigation nationwide. For example, Dr. Moline gave testimony discussing her article in a California state court cosmetic talc trial. (See Doc. 369-1.)

The plaintiff's counsel relied on Dr. Moline's article in his closing argument to connect cosmetic talc exposure to asbestos:

"Gosh, does cosmetic talc really cause mesothelioma? Well,
Dr. Moline, she published a paper on this." (Doc. 369-2 at 6-7.)

Dr. Moline has given testimony in many other cosmetic talc cases. (See Doc. 197-1 at 19.) Moreover, other expert witnesses have begun relying on the article for the basis of their opinions. (see, e.g., Doc. 331-13 at 4; Doc. 331-14 at 3; Doc. 331-15 at 3.) [O]ne [expert] describe[ed] it as "the only peer-reviewed paper that [he] know[s]" to support the conclusion that cosmetic talc use by hairdressers releases material amounts of

asbestos into the air. (Doc. 188-14 at 6-7.)⁵ When entering bankruptcy because of cosmetic talc liabilities, one prominent cosmetic talc seller specifically discussed the article's integral role in supporting the plaintiffs' claims. (Doc. 380-1 at 98-99.)

This court finds that with the protective order in place defense counsel in cosmetic talc cases across the country are stymied from effectively cross-examining plaintiff expert witnesses on the article's foundation. The following exchange from Dr. Moline's cross-examination in the California state trial is illustrative:

Q . . . Other than cosmetic talc, you eliminated anybody from your study who might have had other asbestos exposures; is that correct?

A To the best of my knowledge, yes.

Q Okay. And after you published the paper and testified in Congress about the paper, did you come to learn that some of the information regarding one or more of the people in your study was incorrect as published?

A There was a question about one particular individual that I was presented with information about, but I — based on the information that I had, there was — it wasn't determined that they had the — any additional exposure. I'm not sure of any others.

. . . .

 $^{^{5}}$ Evidently, at least one similar peer-review paper was published in the months after the Moline article was released. (See Doc. 282-5.)

Q Did you publish an errata with regard to your paper after you found out that this one plaintiff that was provided to you had other alleged exposures?

A As I said just a minute ago, there was an allegation or there was a -- a comment, but it was shown to be without evidence, so I did not publish an errata based on that one individual.

(Doc. 377-1 at 6.)

Dr. Moline offered no basis for her statement that an errata was unnecessary because the allegation of alternative exposure "was shown to be without evidence." (Id.) Indeed, she did not have to because the protective order effectively shielded the assertion from cross-examination. (See id.) If the order was not in place, then defense counsel in that case-and defense counsel in similar cosmetic talc cases-would be able to establish that Mrs. Bell was one of the individuals the article studied and then challenge Dr. Moline with Mrs. Bell and Plaintiff's workers' compensation claims asserting, under criminal penalty for false statements, that Mrs. Bell was exposed to asbestos at textile job sites. Defense counsel could show that those workers' compensation claims were not adjudicated on the merits, rather they were dismissed without prejudice, (Docs. 333-3, 333-11), weakening the credibility of Dr. Moline's statement that the allegation of alternative exposure "was shown to be without evidence."

Perhaps more significant than this example of a hamstrung cross-examination is the Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993) issue created by concealment of Mrs. Bell's possible exposure. Dr. Moline testified that "based on the information . . . it wasn't determined that [the research subjects] had . . . any additional exposure." (Doc. 377-1 at 6.) Federal Rule of Evidence 702 requires that expert testimony be "based on sufficient facts or data" and be "the product of reliable principles and methods." Relatedly, Daubert imposes a list of factors a court should consider in assessing the reliability of expert testimony, including "the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation." 509 U.S. at 594 (internal citations omitted). Mrs. Bell's assertion that she may have been exposed to asbestos through the textile industry and Dr. Moline's possible rejection of that potential fact are important pieces of information to aid in the assessment of the potential rate of error of the study's assertion that the thirty-three participants had no asbestos exposure other than talcum powder. Similarly, Dr. Moline's possible rejection of evidence of additional exposure goes directly to the issue of standards controlling her study's operation.

Plaintiff quotes Mrs. Bell's diagnosing pathologist who asserted "these requests go far beyond . . . appropriate investigation into scientific merit or arguments that are made in the scientific literature." (Pl.'s Resp. (Doc. 377) at 14 (quoting Doc. 179-8 at 11).) But Plaintiff fails to recite what this doctor considers "appropriate investigation into scientific merit." (Id.)

From this court's perspective, inquiry into the accuracy of facts and assumptions underlying scientific merit is not only an appropriate inquiry, but also necessary and required. "The inquiry envisioned by [Federal] Rule [of Evidence] 702 is
. . . a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission." Daubert,
509 U.S. at 594-95. Even if reliability is examined by a court and deemed sufficient to support admissibility, relevant cross-examination of an expert includes "factual underpinnings [which]
. . . affect the weight and credibility of the witness' assessment." Bresler v. Wilmington Tr. Co., 855 F.3d 178, 195
(4th Cir. 2017) (internal quotation mark omitted) (quoting Structural Polymer Grp. v. Zoltek Corp., 543 F.3d 987, 997 (8th Cir. 2008)).

In this case, a principal factual underpinning of the article is that in all thirty-three cases studied "no identified source apart from the talcum powder" was identified. (Doc. 274-1 at 2.) The absence of any specific information on the identities of the individuals studied precludes inquiry into the basis of the factual underpinning of no known exposure to asbestos other than talcum powder.

This is the reason why AII seeks to vacate the protective order: to be able to challenge the article's fundamental premise that none of the thirty-three individuals had any known alternative asbestos exposures. This is a valid purpose, especially given the groundbreaking nature and widespread influence of the article. Mrs. Bell's workers' compensation claims, and her employment at the textile facilities, is clearly relevant to the article's findings. If presented with Mrs. Bell's workers' compensation claims, Dr. Moline and other expert witnesses for cosmetic talc plaintiffs may be able to persuasively explain that they do not constitute known alternative exposures because the claims never amounted to more than unproven allegations. But at a minimum, defendants in cosmetic talc cases deserve a fair opportunity to explore the weight to be assigned to Dr. Moline's facts and conclusions-an opportunity not previously available due to the absence of

information stemming from the previous cloak of anonymity.

Simply because Dr. Moline and her colleagues may have a good answer as to why the workers' compensation claims do not undermine the article's credibility does not foreclose an otherwise relevant inquiry. Therefore, the first factor—reason for modification of the protective order—weighs heavily in favor of vacating the order.

2. Alternative Means to Acquire the Information

AII quotes language from the Magistrate Judge suggesting that it would be inappropriate in other cases to seek the release of Mrs. Bell's inclusion in the article. (AII's Br. (Doc. 369) at 24 (quoting Doc. 220-2 at 8).) AII argues that if it cannot disclose Mrs. Bell's inclusion in the article in future cases, then "Plaintiff's counsel is essentially given free rein to commit fraud-provided they never disclose Moline as an expert in any of the 32 remaining cases that were included in her study." (Id. at 24-25; see also AII's Reply (Doc. 380) at 13.)

In evaluating whether to modify a protective order, courts must assess whether the movant can "obtain the information in ways other than requesting a modification of the protective order" because "a motion to modify a protective order in order to use material in other litigation should, in most cases, be

the last resort of a party, not the first." SmithKline Beecham, 210 F.R.D. at 168-69. For example, prior to seeking a protective order's modification, a party in the other litigation should seek to obtain the information via a third-party subpoena. See id. "The third-party subpoena route has the added benefit of allowing the court in which the main litigation is pending to make the ruling. This may be particularly appropriate when relevancy of the discovery is a significant issue" because "[t]he court in which the litigation is pending will be in a better position to decide relevancy issues." Id. at 169 n.7. Additionally, "where the material sought would not be discoverable in the collateral litigation . . . the court should be inclined to deny modification" of a protective order. Wright & Miller, supra, § 2044.1.

Here, AII has not alleged that it is devoid of alternative means to acquire the information it seeks. While AII recites the Magistrate Judge's statement that it may be inappropriate in other cases to seek the Northwell Document identifying

Mrs. Bell, (AII's Br. (Doc. 369) at 24 (quoting Doc. 220-2 at 8)), AII never states that it has actually tried and failed to get that document in any other case through the use of a third-party subpoena or any other mechanism. Because "a motion to modify a protective order in order to use material in other

litigation should, in most cases, be the last resort of a party, not the first, "SmithKline Beecham, 210 F.R.D. at 169, this court is wary of vacating the protective order without any allegation that AII has exhausted alternative means. And even if AII had actually tried and failed in another case to get the Northwell Document identifying Mrs. Bell, this court would not be disposed to undercut that ruling by modifying the protective order because "where the material sought would not be discoverable in the collateral litigation" courts "should be inclined to deny modification." Wright & Miller, supra, \$ 2044.1.

Finally, this court notes that even with the protective order in place, defense counsel in other cosmetic talc cases have ascertained that Mrs. Bell was one of the anonymous thirty-three individuals. (E.g., Doc. 340-2 at 5-8.) To do this, they cross-referenced Dr. Moline's congressional testimony, Examining Carcinogens in Talc and the Best Methods for Asbestos Detection:

Hearing Before the Subcomm. on Econ. & Consumer Pol'y of the H.

Comm. on Oversight & Reform, 116th Cong. 8-9 (2019) (statement of Dr. Jacqueline Moline, Professor, Feinstein Institutes for Medical Research at Northwell Health), with her unsealed expert report evaluating Mrs. Bell, (Doc. 205-11). (E.g., Doc. 340-2 at 5-8.) This demonstrates that defendants in other cosmetic talc

Cases have alternative means of acquiring the information that Mrs. Bell was one of the individuals the article studied, undermining AII's insistence that the Northwell Document is needed to establish this fact.

For these reasons, the second factor—alternative means to acquire the information—weighs against vacating the protective order.

3. Type of Protective Order

AII notes that unlike cases where the parties "enter into a protective order prior to a document production to 'facilitate discovery,'" here "the parties did not stipulate to a protective order." (AII's Reply (Doc. 380) at 3-4 (quoting Factory Mut. Ins., 212 F.R.D. at 305).) AII stresses that the document was produced by a third party, and AII has consistently opposed protecting it. (See id.) AII also insists that the protective order shielding the Northwell Document was always intended to be a preliminary ruling as evidenced by the fact that the Magistrate Judge "more than once . . . reminded the parties that

⁶ Further evidence that the Northwell Document is not required to establish this information is that Plaintiff failed to redact a portion of an unsealed filing in this case that directly identifies Mrs. Bell as an article "subject." (Doc. 179 at 5 ("The Court Should Enter a Protective Order . . . Requiring All Copies of Documents Identifying Betty Bell as a Subject Be Destroyed.").)

the protective order was tentative and subject to reconsideration." (Id. at 4.)

Different types of protective orders are granted varying degrees of deference when deciding whether an order should be vacated. See SmithKline Beecham, 210 F.R.D. at 167.

If the protective order has been entered upon an actual finding that the information falls within Rule 26(c) protection, great care should be exercised before modifying a protective order for use outside of the litigation and the court's control. A blanket protective order, on the other hand, often is nothing more than a Fed. R. Civ. P. 29 stipulation between the parties to keep discovery confidential. A party's claimed reliance on such orders to protect confidentiality is, consequently, less than if the party had to make an actual or particular showing of confidentiality in order to obtain the protective order.

Id. (internal citation omitted). Additionally, less "credence
may be given to reliance on . . . temporary pretrial [protective
orders]." Id.

The protective order at issue is not a blanket protective order that was stipulated to by the parties. Rather, it was entered by the Magistrate Judge in response to an opposed Rule 26(c) motion. (Docs. 179, 197; Oral Order 09/25/2020.) That the order was issued upon an actual, particularized finding of good cause entitles the order to more deference. See SmithKline Beecham, 210 F.R.D. at 167.

on the other hand, Plaintiff cannot claim to have reasonably relied on the protective order because the order was pretrial and explicitly temporary. See id. In issuing the order, the Magistrate Judge stated that "[i]f there is any reason to revisit that further . . . then those are matters that the Court can take up once they are briefed and presented." (Doc. 206 at 96.) AII understandably concluded from this and similar statements, (see, e.g., Doc. 360 at 3 ("[T]he Court has only made preliminary determinations regarding confidentiality")), that the protective order was preliminary and "not intended to be a final order," (AII's Br. (Doc. 369) at 4).

Further discrediting any reliance interest Plaintiff may claim in the protective order is that the Northwell Document was not produced in reliance on the order's protection, rather it was produced before the order was issued.

In sum, this third factor—type of protective order at issue—cuts in both directions. Some aspects weigh in favor of Plaintiff: that the order is not a stipulated blanket order but instead a particularized order supported by a good cause finding of confidentiality. Other aspects weigh in favor of AII: that the order was pretrial, expressly preliminary, and Plaintiff cannot claim that the Northwell Document was produced in reliance on the protective order since the order issued after

the document was produced. Therefore, on balance, this court finds this factor to be neutral.

4. Type of Document Sought⁷

AII insists that the information contained in the Northwell Document is not sensitive enough to warrant the protective order. (AII's Br. (Doc. 369) at 18-22.) AII argues that the article cannot be classified as human subject research,

Mrs. Bell had no reasonable expectation of privacy since she placed her health at issue by commencing this lawsuit, and the information contained in the Northwell Document is not HIPPA protected. (Id.) Plaintiff concedes that the Northwell Document is not HIPAA protected but insists that Mrs. Bell qualifies as a human research subject, and thus her identity is entitled to confidentiality protections to prevent "a chilling effect on further research." (Pl.'s Resp. (Doc. 377) at 14, 18-19.)

Northwell shares the chilling effect concern and adds that even if Mrs. Bell herself is not a human research subject, the article as a whole still qualified as human subject research

⁷ Some cases have examined whether a document is a "judicial document" under this fourth factor. <u>E.g.</u>, <u>SmithKline Beecham</u>, 210 F.R.D. at 167-68. This court found it analytically more logical to address that as a threshold question prior to discussing the four factors. Thus, this court has already concluded that the Northwell Document is not a judicial document and will examine other concerns within the confines of the fourth factor.

because of the other individuals studied. (Northwell's Resp. (Doc. 392) at 15-16.)

When the documents under protective order are highly confidential, "[t]he court may demand greater need for modification and act with more reluctance" when faced with a modification motion. SmithKline Beecham, 210 F.R.D. at 168. In contrast, "when the documents at issue do not likely involve highly confidential information . . . opposition to modification carries less weight." Id. at 167. In determining what information qualifies as "highly confidential," "some documents or information will, at initial apprehension, intuitively appear to be more confidential." Id. at 167-68.

United States Department of Health and Human Services regulations confer upon "human subject" research confidentiality protections enforced by an IRB. See, e.g., 45 C.F.R.

§ 46.111(a)(7) (2020). "Human subject" is defined as "a living individual about whom an investigator . . . conducting research . . . [o]btains information . . . through intervention or interaction with the individual, and uses, studies, or analyzes the information or . . . [o]btains, uses, studies, analyzes, or generates identifiable private information." Id. § 46.102(e)(1) (emphasis added).

Mrs. Bell does not qualify as a human subject under that regulation because by the time Dr. Moline and her coauthors "obtain[ed]," "use[d]," "studie[d]" "analyze[d]," or "generate[d]," Mrs. Bell's information for purposes of drafting

 $^{^{8}}$ As an initial matter, Northwell appears to concede that because Dr. Moline's study was not conducted by or on behalf of the federal government these protections for human subjects do not inherently apply. (Northwell's Resp. (Doc. 392) at 14-15.) Rather, Northwell insists the protections apply because it has voluntarily elected, as part of its "Federalwide Assurance" to the government, to have these protections apply to all its human subject research-regardless of the source of support or funding for that research. (Id.) Northwell's concession that these protections only apply because it has chosen to apply them (and has told the government about that choice), suggests to this court that these protections are not requirements imposed on Northwell by the government, but rather requirements it has imposed upon itself. Thus, nonenforcement of these protections would not seem to violate any federal requirements the government itself has imposed on Northwell.

the article, Mrs. Bell was no longer a "living individual." Id.

Mrs. Bell died in June 2017. (Doc. 39-2 at 2.) Dr. Moline and

her coauthors did not receive IRB approval for their study until

March 2018. (Doc. 265-1 ¶ 17; Doc. 392-1.) However, it seems

likely that some of the other individuals the article studied

were living when IRB approval was granted—thus qualifying them

as human subjects. Indeed, Northwell claims at least twenty—

three individuals studied were still living when the study was

conducted. (Northwell's Resp. (Doc. 392) at 15.) Irrespective of

the exact number of living individuals, the fact that at least

some of the individuals studied were alive when the IRB reviewed

the article's application is corroborated by the IRB approval's

statement that the "research must be conducted in accordance

with . . Department of Health and Human Services regulations

⁹ Northwell has not provided any evidence to substantiate this number, preventing this court from independently corroborating Northwell's claim.

CFR 46," which provides protection for human research subjects. 10 (Doc. 392-1 at 3; accord Doc. 265-1 \P 20.)

Thus, although the article as a whole likely qualified as human subject research, Mrs. Bell herself was never a human subject because she was deceased by the time the study began. While being part of a larger study that qualified as human subject research may have facially and incidentally granted Mrs. Bell greater confidentiality protections, this court is hesitant to give much weight to those protections that were not crafted with the goal of protecting the privacy of deceased individuals like Mrs. Bell. This is consistent with caselaw that indicates Mrs. Bell's privacy interest in her study participation was always, and remains presently, diminished because she was deceased. (MJ's Order (Doc. 309) at 7 n.2 (citing Wessler v. DOJ, 381 F. Supp. 3d 253, 259 (S.D.N.Y. 2019)). That Mrs. Bell was not a human subject also renders inapposite the caselaw Plaintiff has marshalled, as well as much

The IRB approval also waived the requirement that Dr. Moline and her coauthors acquire informed consent from the individuals to be studied. (See Doc. 392-1 at 2.) Northwell explains this informed consent waiver was granted because the IRB found Dr. Moline's research subjects faced no more than "a minimal risk of harm resulting from a breach of confidentiality." (Northwell's Resp. (Doc. 392) at 14 (citing 45 C.F.R. § 46.117(c)(1)(ii) (2020)).) That finding undercuts Northwell and Plaintiff's argument that research subjects would suffer great harm if their identities were disclosed.

of the regulatory scheme that Northwell exhaustively recites.

(See Pl.'s Resp. (Doc. 377) at 14 (citing Lampshire v. Procter & Gamble Co., 94 F.R.D. 58 (N.D. Ga. 1982); Doe v. Am. Red Cross Blood Servs., 125 F.R.D. 646 (D.S.C. 1989)); see Northwell's Resp. (Doc. 392) at 9-18.)

Moreover, since Mrs. Bell was not a human subject, that invalidates Plaintiff and Northwell's argument that the disclosure of human subjects would have a chilling effect on academic research. (See Pl.'s Resp. (Doc. 377) at 14; Northwell's Resp. (Doc. 392) at 12-13.) Here, no human subject's identity is being disclosed. Additionally, as to Plaintiff and Northwell's chilling effect concern, this court remains ever "cognizant that 'the ability to conduct probing scientific and social research supported by a population willing to submit to in-depth questioning' depends on the guarantee that the researcher will take steps to ensure confidentiality." (MJ's Order (Doc. 309) at 5 (quoting Farnsworth v. Procter & Gamble <u>Co.</u>, 758 F.2d 1545, 1547 (11th Cir. 1985)).) But Northwell's argument that "[f]orcing the disclosure of the identities of research subjects . . . would significantly dissuade individuals from agreeing to participate in human subject research," neglects the fact that Mrs. Bell never agreed to participate in Dr. Moline's research because the study was not required to

obtain informed consent from any of the individuals studied. (See Doc. 392-1 at 2.)

Critically, the Northwell Document redacts all information on other individuals, (see Doc. 331-17), some of whom likely qualify as human subjects thus entitling them to greater confidentiality protections than Mrs. Bell. Additionally, the information the Northwell Document contains is not sensitive; all that is listed is Mrs. Bell's name, the brands of talc she used, the name of the law firm representing her, her occupation, and her mesothelioma diagnosis date. 11 (Id.) Given Mrs. Bell put all that information at issue by filing this lawsuit, that information is a far cry from the sort of document or information that "at initial apprehension, intuitively appear[s] to be more confidential." SmithKline Beecham, 210 F.R.D. at 168. In fact, all the information in the Northwell Document-and indeed much more sensitive medical information—is already contained in this case's publicly available filings. (See, e.g., Doc. 205-11.) Consequently, this court finds that Mrs. Bell's privacy interests do not justify keeping the Northwell Document confidential.

 $^{^{11}}$ The Northwell Document appears to have made a clerical error as to Mrs. Bell's diagnosis date. It states she was diagnosed with mesothelioma on "7/20/2016." (Doc. 331-17 at 6.) She was actually diagnosed a year earlier. (Doc. 322-2 at 2; Doc. 205-11 at 4-5.)

Moreover, AII and Plaintiff agree that none of the information in the Northwell Document is HIPAA protected. (Compare AII's Br. (Doc. 369) at 21, with Pl.'s Resp. (Doc. 377) at 19.) Plaintiff's concession that no HIPPA-protected information is at risk of disclosure nullifies Northwell's argument that "vacating the protective order would violate the purpose of HIPPA." (Northwell's Resp. (Doc. 392) at 17 (capitalization removed).) As Northwell acknowledges, the relevant purpose of HIPPA is to benefit patients by providing privacy protections for certain types of health information. (See id. at 17 (citing 45 C.F.R. §§ 160.103, 164.502, 164.508 (2020)).) Here, the patient's representative, Plaintiff, concedes no HIPPA-protected information is at risk of disclosure. In light of this concession-not to mention the HIPPA waiver Plaintiff executed, (Doc. 179-6)-HIPPA does not seem to apply nor is its purpose violated.

In that vein, this court reminds Northwell that despite its claimed "significant interest in protecting the anonymity of research participants," (Northwell's Resp. (Doc. 392) at 12), it "does not appear to have any remaining privacy interest in the fact of Ms. Bell's participation in Dr. Moline's study," (MJ's Order (Doc. 309) at 7). That is because "[i]n a medical research study, the interest in confidentiality belongs primarily to the

study participant, not the researcher or sponsoring facility."

(Id.) Here, that study participant chose to publicly expose the fact of her mesothelioma by filing a complaint in this case,

(Doc. 1), and the workers' compensation claim she chose to file, alleging she was exposed to asbestos in the textile industry, is publicly available, (See Doc. 322-2).

Finally, this court notes that AII seeks to vacate the protective order to un-shield a single document. This matters because it can "make a difference if the proposed modification involves one or many documents." SmithKline Beecham, 210 F.R.D. at 168. While courts may be inclined to reject motions to vacate protective orders when a large number of documents would be "wholesale release[d]," "request[s] for modification only involv[ing] a limited set of documents" are more palatable. Id.

For these reasons, this court concludes that the final factor—type of document sought—weighs in AII's favor. Because the first factor weighed in AII's favor, the second in Plaintiff's favor, and the third was neutral, this last factor tips the scales decisively and establishes that AII has discharged its burden of showing good cause to vacate the

protective order. 12 Accordingly, this court will grant AII's Motion to Vacate the Preliminary Protective Order of September 25, 2020. (Doc. 368.)

At this time, this court will not unseal any filings as AII's motion has not sought such action. If any party seeks to unseal any filings pursuant to this decision vacating the protective order, they should file the appropriate motion with this court.

C. Motions to Seal

AII's motion to vacate and the related briefing are all accompanied by corresponding motions to seal. (Docs. 370, 375, 378, 381, 390, 395.) AII and WCD explicitly state that they do not believe the motion or briefing should be sealed but have filed the motions because "Plaintiff and Northwell have claimed confidentiality with regard to certain information." (Doc. 370 at 1; see also Doc. 375.) Plaintiff effectively acknowledges that if the motion to vacate the protective order is granted, then the motions to seal should be denied. (See Doc. 382 at 1 (recognizing that the motions to seal are contingent on "the

¹² Alternatively, this court further finds the first factor weighs substantially in AII's favor. This court goes so far as to find the reason and purpose for the modification establish an extraordinary circumstance and a related compelling need. See S.E.C. v. TheStreet.com, 273 F.3d 222, 229 (2nd Cir. 2009). As a result, even if the third factor weighed in Plaintiff's favor, this court would reach the same result.

Court's decision as to whether the protective order should be vacated"); see also Doc. 374 at 1-2.)

Because this court has decided that the Northwell Document is not entitled to confidentiality protections and thus will grant the motion to vacate the protective order, <u>supra</u> Section II.B., the motions to seal will all be denied. This court will seal and stay this order for 7 days to allow Plaintiff and Intervenor to review this order and determine how they wish to proceed.

III. CONCLUSION

For the foregoing reasons,

IT IS THEREFORE ORDERED that Northwell's Motion for

Reconsideration of its Motion to Intervene and Extend Protective

Order, (Doc. 388), is GRANTED insofar as Northwell is hereby

admitted to the case as an intervening party.

IT IS FURTHER ORDERED that AII's Motion to Vacate the Preliminary Protective Order of September 25, 2020, (Doc. 368), is GRANTED.

IT IS FURTHER ORDERED that the motions to seal the motion to vacate and the related briefing, (Docs. 370, 375, 378, 381, 390, 395), are all DENIED.

This order is hereby **SEALED** and **STAYED** for 7 days. At the conclusion of the 7 days, this order shall be **UNSEALED** by the Clerk unless a further order is entered.

This the 13th day of September, 2022.

United States District Judge